

§ 878.4494

coated; and it may be undyed or dyed with an FDA-approved color additive. Also, the suture may be provided with or without a standard needle attached.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

[56 FR 47151, Sept. 18, 1991, as amended at 68 FR 32984, June 3, 2003]

§ 878.4494 Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.

(a) *Identification.* An absorbable poly(hydroxybutyrate) surgical suture is an absorbable surgical suture made of material isolated from prokaryotic cells produced by recombinant deoxyribonucleic acid (DNA) technology. The device is intended for use in general soft tissue approximation and ligation.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology." For the availability of this guidance document see § 878.1(e).

[72 FR 43146, Aug. 3, 2007]

§ 878.4495 Stainless steel suture.

(a) *Identification.* A stainless steel suture is a needled or unneedled non-absorbable surgical suture composed of 316L stainless steel, in USP sizes 12-0 through 10, or a substantially equivalent stainless steel suture, intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

[65 FR 19836, Apr. 13, 2000, as amended at 68 FR 32984, June 3, 2003]

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§ 878.4520 Polytetrafluoroethylene injectable.

(a) *Identification.* Polytetrafluoroethylene injectable is an injectable paste prosthetic device composed of polytetrafluoroethylene intended to be used to augment or reconstruct a vocal cord.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3.

§ 878.4580 Surgical lamp.

(a) *Identification.* A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.

(b) *Classification.* Class II.

§ 878.4630 Ultraviolet lamp for dermatologic disorders.

(a) *Identification.* An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photoactivate a drug in the treatment of a dermatologic disorder if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.

(b) *Classification.* Class II.

§ 878.4635 Ultraviolet lamp for tanning.

(a) *Identification.* An ultraviolet lamp for tanning is a device that is a lamp (including a fixture) intended to provide ultraviolet radiation to tan the skin. See § 1040.20 of this chapter.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4660 Skin marker.

(a) *Identification.* A skin marker is a pen-like device intended to be used to